



Council of State and Territorial Epidemiologists

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February 11, 2000

FDA/Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
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Docket No. 97N-0074

USDA/FSIS
USDA/FSIS Hearing Clerk,
300 12th St., SW., Rm. 102 Cotton Annex,
Washington, DC 20250-3700.
Docket No. 98-045N

Environmental Protection Agency
Docket No. OPP-00550B; FRL-6399-8

Re: President's Council on Food Safety Strategic Plan

Federal Register Announcement: December 15, 1999 (Volume 64, Number 240)

The Council of State and Territorial Epidemiologists (CSTE) is pleased to provide the following comments on the President's Council on Food Safety's comprehensive national food safety strategic plan.

The goal of the President's Food Safety Initiative (FSI) is to apply the collective resources of government, industry, consumer and academia, to reduce, to the greatest extent possible, the incidence of foodborne illness. Meeting this goal requires every link in the food production, food processing and food preparation chain to re-examine its effort to assure the safety of the food supply. The FSI also calls for collaboration between public and private organizations and improved coordination within government agencies at the federal, state and local levels. As has been recognized in the National Academy of Sciences report, "Ensuring a Safe Food Supply", state and local agencies have major responsibilities and commitment of resources in delivering food safety activities in the United States. Federal agency decisions will have a major impact on state and local budgets and program activities.

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CSTE was organized in the early 1950's in response to the need to have at least one senior person in each state and territory responsible for public health surveillance of diseases and conditions of public health significance. Since then, CSTE has grown to include members from every U.S. State and territory, Canada, and Great Britain. Almost 400 epidemiologists are now members. The surveillance and epidemiology of infectious diseases, chronic diseases and conditions, injuries and environmental health concerns are priority areas for CSTE. Over 150 members serve as special topic consultants for a broad range of public health concerns such as food safety.

In all 50 states and territories, state and local epidemiologists located in health departments perform a number of important responsibilities that ensure the safety of the national food supply. This includes monitoring the occurrence of foodborne illnesses, investigating outbreaks and unusual reports of food-related illnesses, formulating state policies addressing food safety, and in general, serving as a quality assurance component or feedback mechanism by which to judge the effectiveness of food safety regulatory activities. In this context, the members of CSTE provide a unique perspective for the federal strategic plan and we wish to make the following comments regarding the valuable role of epidemiologists and their importance in ensuring a safe and healthy food supply.

Comments related to the entire plan and the "Vision" and "Overarching Goals" statements:

- CSTE commends the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA) for undertaking in partnership an ambitious but critically important effort to improve the nation's food safety system. We appreciate the first steps toward recognition that states and localities are essential partners in this effort.
- CSTE suggests that the strategic plan should represent national planning towards food safety. Understanding the original intention of the President's executive order towards a unified federal budget for food safety, we do wish to re-emphasize the important role this strategic plan will have in focusing national efforts at the state, local and tribal levels towards food safety. Specific mention of the word "national" in overarching goal statements would go a long way toward recognizing this interdependence.
- CSTE supports the current framework of the Federal Food Safety Strategic Plan as stated in the January 7th, 2000 draft. The three goals of science and risk assessment, risk management, and risk communication adequately encompass the spectrum of food safety issues.
- CSTE recommends that the federal strategic plan's "Vision Statement" incorporate wording to recognize the importance of prompt responses to foodborne illness and outbreaks to the protection of the public's health.

Comments related to the "Science and Risk Assessment" Goal:

- CSTE supports Objective 2 under the "Science and Risk Assessment" section and urges our federal partners to help strengthen local and state health department surveillance capacity. All state and local public health agencies conduct activities to encourage reporting of human illnesses. These activities are collectively termed "surveillance" and there are a variety of techniques that may be used to enhance the productivity of this reporting. All 50 states and the US territories have established reportable disease notification laws that begin the information flow to local and state officials. It is

this system of reporting combined with other novel techniques that allows for the detection of established and new microbial food illnesses. These activities represent both a critical step in protecting the public's health and a mechanism by which to judge the effectiveness of new or existing food agency regulatory activities.

- CSTE believes that the document should explicitly note that "risk assessment" in this context includes basic epidemiology. Epidemiology cannot be excluded in development of safety policies or in regulatory decisions. The epidemiologic techniques used in outbreak investigation and in disease control and prevention activities are based on sound science and serves as the backbone of state and local risk assessment as applied to food safety.
- In keeping with the above consideration, CSTE suggests that the term "surveillance" be more clearly defined in order to provide better clarity. While the term "surveillance" is well recognized in epidemiology, referring to efforts to identify incident cases of human illness, it is not clear that this definition is at the heart of some objectives and activities. Surveillance can also mean efforts to detect disease in animal populations, pathogens within food specimens, criminal activities among individuals using foodborne pathogens for terrorism and other meanings. We suggest using the phrase "surveillance for adverse human health outcomes" as the preferable term for this document, consistent with Objective 2.
- With respect to Objective 4 of the "Science and Risk Assessment" goal and Objective 3 of the "Risk Management" goal, CSTE agrees that there is significant benefit from the development and use of rapid laboratory tests for pathogenic microorganisms in food and clinical specimens. However, the investigation and control of foodborne disease and foodborne outbreaks, and the prevention of future foodborne outbreaks, require that the appropriate testing of food and clinical specimens be conducted. The implementation of necessary public health interventions, identification of foods responsible for outbreaks, identification of statewide and multistate food outbreaks, and identification of pathogen(s) responsible for an outbreak require certain critical information obtained from laboratory testing. Rapid tests for pathogenic microorganisms may fail to provide this critical information needed by public health officials. Therefore, CSTE strongly recommends that the relevant Action Items in these Objectives clearly state that any rapid tests that are developed should be employed to supplement, not replace, existing laboratory testing.

Comments related to the "Risk Management" Goal:

- CSTE supports the first action item under Objective 8 of the "Risk Management" section in building the infrastructure of state and local health department epidemiology capacity. Each day in this nation, public health sanitarians, nurses and epidemiologist receive reports of foodborne illness from members of the public, institution officials, health care providers and others. In response, these public health officials investigate by directly contacting the affected individual(s) and/or their health care providers. Their efforts to obtain food intake histories and the corresponding epidemiologic links that may be identified constitute the most critical step in detecting illness and outbreaks. Considerable investment is needed to ensure a competent response by these agencies to outbreaks. While CDC cooperative agreement initiatives such as the Emerging Infections Program, Bioterrorism Preparedness, and the Epidemiology and Laboratory Capacity programs have focused the attention of key policy makers and the nation on the important role played by new microbial pathogens, both naturally occurring and intentional, these activities have only gone part-way in providing help with this needed basic capacity. While funding has been made available to support some state and local

specialty food safety activities under each of these initiatives, the support has not allowed for the building of a basic core level of investigative capacity of all the US states and territories. CSTE supports further efforts to fund basic epidemiologic core infrastructure and efforts to build the personnel workforce performing field epidemiologic investigations.

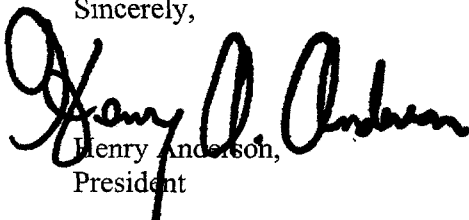
- CSTE suggests that the terms "Tracebacks" and "Tracing" as written in the Risk Management section Objective 8, be more clearly defined, CSTE prefers that the document identify and define two distinct types of traceback activities, those for regulatory purposes and those for epidemiologic purposes. As has been shown in a number of state and multi-state outbreaks, regulatory tracebacks and epidemiologic tracebacks differ in their ultimate goals. Regulatory tracebacks seek to establish sufficient legal evidence to justify federal regulatory action, while epidemiologic tracebacks seek to strengthen the specificity of an association between a food agent and illness. Epidemiologic traceback activities may require less stringent legal standards in order to prompt state, local or tribal notifications or warnings about a food agent. CSTE wishes to promote the understanding of the dual roles of tracebacks in food outbreak investigations and, consequently, suggests using the terms "regulatory-traceback activities" and "epidemiologic-traceback activities" in this objective.

Comments related to the "Organizational Considerations" Section:

- CSTE supports the work of the Foodborne and Diarrheal Diseases Branch of the Centers for Disease Control and Prevention (CDC) and wishes to make clear our interest in seeing this agency's epidemiology and laboratory activities remain separate from any unified federal regulatory agency. The CDC epidemiologists and laboratorians, in cooperation with state health departments, have investigated and helped respond to many of the most important microbial and chemical food safety concerns over the past decades. These epidemiologic investigations have provided key scientific evidence to guide policy on subjects as widespread as the detection of *E. coli* O157:H7 as an emerging food pathogen in meats and unpasteurized juice, the detection of widespread illness from *Campylobacter* and *Salmonella* occurring from the consumption of undercooked eggs and egg products, *Vibrio* species in shellfish, and many other food hazards. CSTE feels that the federal strategic plan must acknowledge that the citizens of the United States have been well served by CDC and state health department epidemiology programs remaining independent of federal regulatory and agricultural promotion efforts. It is through this separation of functions that the public is assured of aggressive and prompt detection of foodborne and waterborne disease threats.

CSTE appreciates the opportunity to comment on this draft of the federal food safety strategic plan. If our organization can be of further help in this effort, please contact Dr. Jesse Greenblatt, State Epidemiologist for the New Hampshire Department of Health and Human Services, our liaison for this initiative, at (603) 271-4477.

Sincerely,



Henry Anderson,
President

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